

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/090,418	EDWARDS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/5/2005.
2. ☒ The allowed claim(s) is/are 1, 2 and 4-11. (renumbered as 1, 2 and 3-10)
3. ☒ The drawings filed on 28 March 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>7/16/2004</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                                | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9. <input type="checkbox"/> Other _____.   |

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### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Caroyln S. Elmore on May 5, 2005.

1. Amend the Claims as follows:

#### IN THE CLAIMS:

Cancel claims 19-21 without prejudice.

In claim 1, line 9, after the phrase "at least 4 hours" insert - - - and the particles having a tap density less than about  $0.4 \text{ g/cm}^3$  - - - - -.

In claim 10, line 8, after the phrase "4 hours" insert - - - - and the particles having a tap density less than about  $0.4 \text{ g/cm}^3$  - - - - -.

In claim 11, line 7, after the phrase "4 hours" insert - - - - and the particles having a tap density less than about  $0.4 \text{ g/cm}^3$  - - - - -.

#### Remarks

The above amendment places this case in condition for allowance.

**Reasons for Allowance:**

The following is an examiner's statement of reasons for allowance: The claims are allowable over the cited prior art because the prior art does not teach, disclose nor make obvious the claimed method of increasing systemic bioavailability of a hormone administered by inhalation comprising: administering to the respiratory system of a patient or animal in need of said hormone aerodynamically light particles that have a mass mean diameter greater than 5  $\mu\text{m}$ , an aerodynamic diameter less than 4.7  $\mu\text{m}$  and that include said hormone, wherein the particles are delivered and deposited to the patient's or animal's lungs and the hormone is released in the patient's or animal's blood stream for at least 4 hours and the particles having a tap density less than about 0.4  $\text{g}/\text{cm}^3$ .

The prior art of record, Platz et al. (U.S. Patent No. 6,423,344B1) teaches a method of delivering therapeutic agents such as insulin along with pharmaceutical carriers and excipients to the lung of a patient particles having a mass mean diameter. However, Platz et al. does not teach the release profile of the insulin composition and the specified tap density set forth in claims 1, 10 and 11. Applicants have shown in the Appeal brief filed on December 17, 2004, page 10 that the examples of Platz illustrates that the combination of large geometric diameters, low density and low aerodynamic diameters is not described or taught by Platz and accordingly, Platz does not teach or suggest the unique combination of particle characteristics, generically or specifically, claimed in instant Application.

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The terminal disclaimer filed on August 2, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of prior Patent No.s 5,874,064; 5,855,913; 6,436,443; 5,985,309; 6,503,480; and 6,254,854 has been reviewed and is accepted. The terminal disclaimer has been recorded.

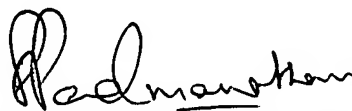
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan  
Supervisory Examiner  
Art Unit 1617

Jmk  
May 11, 2005